STILLMEADOW
INCORPORATED

VOLUME __ OF __ OF SUBMISSION

Niccanon ZP700

FINAL REPORT

ACUTE ORAL TOXICITY STUDY (UDP) IN RATS

OCSPP NO. 870.1100 and OECD 425

AUTHOR:

Janice O. Kuhn, PhD, DABT

STUDY INITIATION DATE: 10 January 2012
STUDY COMPLETION DATE: 13 June 2012

CONDUCTED BY:
STILLMEADOW, Inc.
12852 Park One Drive
Sugar Land, TX 77478

LABORATORY STUDY NUMBER:

15886-11

VOLUME 1 OF 1 OF STUDY

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SPONSOR:
Nicca USA, Inc.
c/o Arch Chemicals
501 Merritt 7
Norwalk, CT 06856

STATEMENT OF NO DATA CONFIDENTIALITY CLAIM

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10 (d) (1) (A), (B) or (C).

Company: Nicca USA, Inc.

Company Agent: _____ Date: _____

Title _____ Signature _____

These data are the property of Nicca USA, Inc., and as such, are considered to be confidential for all purposes other than compliance with FIFRA § 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality that may exist under any other statute or in any other country.

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with United States Environmental Protection Agency FIFRA 40 CFR 160 with exception of:
Section 160.31 (d) and 160.105 (a) The provided Certificate of Analysis was not accompanied by a GLP compliance statement.
Section 160.31 (d) and 160.105 (b)(e) Stability information was not provided to the testing facility.

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with United States Environmental Protection Agency TSCA 40 CFR 792 with exception of:
Section 792.31 (d) and 792.105 (a) The provided Certificate of Analysis was not accompanied by a GLP compliance statement.
Section 792.31 (d) and 792.105 (b)(e) Stability information was not provided to the testing facility.

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with Organization for Economic Cooperation & Development Principles of GLP, Annex 2, C(98)17 with exception of:
Section II, 1.1 (2)(p), 6.1 (1) and 6.2 (2) The provided Certificate of Analysis was not accompanied by a GLP compliance statement.
Section II, 6.2 (4) Stability information was not provided to the testing facility.

Janice O. Kuhn

Janice O. Kuhn, PhD, DABT
Study Director, STILLMEADOW, Inc.

13 Jun 12
Date

Nicholas P. Skoulis

Signature of Agent of Sponsor

15 June 12
Date

Nicholas P. Skoulis

Agent Name
Sponsor: Nicca USA, Inc.

Signature of Agent of Submitter

Date

Agent Name
Submitter: Arch Chemicals

QUALITY ASSURANCE STATEMENT

Test Substance: Niccanon ZP700
Study Title: Acute Oral Toxicity Study (UDP) in Rats

The study report and data have been audited in accordance with Good Laboratory Practice Standards and STILLMEADOW, Inc. Standard Operating Procedures (SOPs). The final report accurately reflects the study data. The Quality Assurance Unit has not been involved in the actual conduct of this study.

The Quality Assurance Unit performed a recent facility inspection on 23 Jan 12. All findings were reported to Management, and the report and responses are kept in the Quality Assurance files.

The findings from any study inspections and audits were reported to the Study Director and Management as follows:

Critical Phase Inspected	Date Inspected	Reported to Study Director	Reported to Management
Protocol Review	20 Dec 11	20 Dec 11	20 Dec 11
Observations/Body Wt/Necropsy	4 Apr 12	4 Apr 12	4 Apr 12
Report/Data Audit	16 May 12	16 May 12	16 May 12

Ajeena Joy

Ajeena Joy, BS
Quality Assurance, STILLMEADOW, Inc.

13 Jun 12
Date

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SUMMARY

The test substance, Niccanon ZP700, was evaluated for its acute oral toxicity potential in female albino rats when administered as a gavage dose at a level of 5000 mg/kg. Since the test substance failed the limit test, the main test was conducted following the up-and-down procedure (UDP) at 175, 550 and 1750 mg/kg. The study was terminated following the stopping rules of this procedure. Mortality occurred at all levels. Clinical signs included activity decrease, diarrhea, piloerection, polyuria, ptosis and sensitivity to sound; surviving animals were asymptomatic by Day 2. Animals surviving to termination exhibited weekly weight gain during the study. Abnormal necropsy findings that occurred, only in the animals dying on test, pertained to abdominal/tail areas, liver and contents of the gastrointestinal tract. The acute oral LD_{50} was estimated to be 481 mg/kg.

INTRODUCTION

The objective of this study was to assess the acute oral toxicity potential of the test substance when administered by gavage to rats in accordance with US EPA OCSPP 870.1100, which is intended to meet testing requirements of FIFRA 7 USC 136, et seq, and TSCA 15 USC 2601; and OECD 425. This study was conducted for Nicca USA, Inc., according to the approved protocol and STILLMEADOW, Inc. SOPs. There were no deviations from the protocol that affected the quality or outcome of the study. All procedures used in this study are in compliance with Animal Welfare Act Regulations. The protocol, raw data, this report and a sample of test substance are archived at STILLMEADOW, Inc. The study was initiated on 10 Jan 12, the pre-dose experimental portion began on 12 Mar 12, and the animals were treated as follows.

Dose Level (mg/kg)	Treatment		Animal Number	In-life Termination Date
	Date	Time		
5000	13 Mar 12	1107	51	15 Mar 12
175	15 Mar 12	1149	52	29 Mar 12
550	16 Mar 12	1136	53	19 Mar 12
175	19 Mar 12	1035	54	21 Mar 12
550	21 Mar 12	0950	55	4 Apr 12
1750	23 Mar 12	1018	56	24 Mar 12
550	26 Mar 12	1036	57	9 Apr 12
1750	28 Mar 12	1105	58	30 Mar 12
550	30 Mar 12	1103	59	13 Apr 12
1750	10 Apr 12	1138	60	12 Apr 12